



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	387381	BioFem
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Biomedica Nutraceuticals Pty Ltd	
<b>Postal Address</b>	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
<b>ARTG Start Date</b>	22/04/2022	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

### Products

#### 1 . BioFem

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	22/04/2022
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### Permitted Indications

- Maintain/support energy production
- Maintain/support general health and wellbeing
- Maintain/support healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Aid/assist thyroid hormone production
- Maintain/support muscle function
- Support healthy stress response in the body
- Maintain/support nervous system health
- Maintain/support nervous system function
- Support healthy emotional/mood balance in premenstrual woman
- Support healthy emotional/mood balance
- Maintain/support female healthy hormonal balance
- Maintain/support female healthy hormonal balance during the reproductive cycle
- Maintain/support female reproductive system health
- Traditionally used in Western herbal medicine to haemagogue/emmenagogue/promotes menstrual flow
- Decrease/reduce/relieve menstrual cycle irregularity/irregular periods
- Maintain/support/regulate healthy menstrual cycle
- Decrease/reduce/relieve hot flushes associated with menopause
- Maintain/support skin health

### Indication Requirements

- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to any thyroid related diseases.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to abortifacient action.
- If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Crocus sativus stigma Dry</b>	<b>13.5 mg</b>
Equivalent: Crocus sativus (Dry)	45 mg
<b>magnesium amino acid chelate</b>	<b>250 mg</b>
Equivalent: magnesium	50 mg
<b>potassium iodide</b>	<b>98.1 microgram</b>
Equivalent: iodine	75 microgram
<b>pyridoxine hydrochloride</b>	<b>60.78 mg</b>
Equivalent: pyridoxine	50 mg
<b>selenomethionine</b>	<b>186.3 microgram</b>
Equivalent: selenium	75 microgram
<b>Vitex agnus-castus fruit Extract dry concentrate standardised</b>	<b>100 mg</b>
Equivalent: Vitex agnus-castus (Dry)	1000 mg
<b>zinc amino acid chelate</b>	<b>25 mg</b>
Equivalent: zinc	5 mg

**Other Ingredients (Excipients)**

- calcium hydrogen phosphate dihydrate
- colloidal anhydrous silica
- dextrin
- hypromellose
- magnesium stearate
- maltodextrin
- microcrystalline cellulose

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